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MAIL STOP AMENDMENT
Attorney Docket No. 23233YXY

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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In re Application of:

HERMELIN et al. Examiner: ALSTRUM ACEVEDO, J. H.

Serial No.: 10/644,041 Group Art Unit: 1616

Filed: August 20, 2003 Conf No.: 5080

For: **MAXIMIZING EFFECTIVENESS OF SUBSTANCES USED TO IMPROVE HEALTH AND WELL BEING**

TRANSMITTAL LETTER

Commissioner for Patents
Box 1450
Alexandria, VA 22313-1450

Sir:

Submitted herewith for filing in the U.S. Patent and Trademark Office is the following:

(1) Transmittal Letter; and
(2) Response to Official Action dated August 31, 2006.

The Commissioner is hereby authorized to charge any deficiency or credit any excess to Deposit Account Number 14-0112.

Respectfully submitted,

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Date: November 29, 2006

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Mail Stop Response
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RESPONSE TO OFFICIAL ACTION DATED AUGUST 31, 2006

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This is in response to the Office Action dated August 31, 2006. The three-month shortened statutory period for response is set to expire on November 30, 2006. Accordingly, this response is timely filed.

SUMMARY OF RESTRICTION/ELECTION REQUIREMENT

The Examiner has required restriction under 35 U.S.C. §§ 121. An election must be made to a single invention to which the claims must be restricted, as follows:

Group I: Claims 1 and 239-281, drawn to a drug regimen comprising an active therapeutic substance selected from vitamins, minerals, and combinations thereof administered multiple times during at least one 24-hour period, classified in class 514, subclass 52+, depending on the substance selected.

Group II: Claims 282-296, drawn to a method of enhancing the therapeutic effect of an active substance selected from vitamins and minerals, classified in class 702, subclass 19 and 23.

Group III: Claims 297-301, drawn to a pharmaceutical composition for optimizing therapeutic activity comprising (1) a first active component selected from water-soluble vitamins and water-soluble minerals and (2) a second component selected from water-insoluble vitamins and water-insoluble minerals, classified in class 424, subclasses 600-606, 630, 646-647, 673, 680-681, 708, etc.

Additionally, if Groups I or II are elected, the Examiner has required the species election of a single specific: (1) dosage form from those recited in claim 248, (2) vitamin, (3) mineral, and (4) method of administration.

PROVISIONAL ELECTION

Applicants hereby provisionally elect the claims of Group I, claims 1 and 239-281, drawn to a drug regimen comprising an active therapeutic substance selected from vitamins, minerals, and combinations thereof administered multiple times during at least one 24-hour period, with traverse.

Further to the requirement of a species election, Applicants hereby provisionally elect the following: (1) tablets as the dosage form from those recited in claim 248, (2) folic acid as a vitamin, (3) calcium as the mineral, and (4) immediate release as the method of administration.

TRAVERSAL

Applicants respectfully traverse the Examiner's requirement for election.

First, MPEP § 803 specifies that restriction/election between two groups of claims is only proper when (1) one group of claims is independent ***or*** distinct from another group of claims and (2) a "serious burden" exists on the examiner in examining both groups of claims.

The Examiner can show a "serious burden" by establishing one of: the inventions are classified separately; the inventions have been classified together, but it can be shown that each subject has formed a separate subject for inventive effort (can cite patents or show a separate field of search); or the inventions require a separate field of search, that is, it is necessary to search for one subject in a place where no

pertinent art for the other subject exists (MPEP § 808.02 (c)).

In the present application, the restriction requirement is traversed because it omits "an appropriate explanation" as to the existence of a "serious burden" if a restriction were not required between Groups I-III or the species asserted. *See* MPEP § 803. A complete and thorough search for the invention set forth in all of the alleged Groups would require searching the art areas appropriate to the other Groups. Since a search of each of the inventions of Groups I-III, as well as the corresponding asserted species, would be coextensive, it would not be a *serious* burden upon the Examiner to examine all of the claims in this application.

Further, at the Examiner's disposal are powerful electronic search engines providing the Examiner with the ability to quickly and easily search all of the claims. Moreover, given the overlapping subject matter, examination of the claims in this application would not pose a serious burden, because the searches would be coextensive.

Additionally, the fact that various claims may fall under different U.S. Patent and Trademark Office classes does not necessarily make them independent or distinct inventions. The

classification system at the U.S. Patent and Trademark Office is based in part upon administrative concerns and is not necessarily indicative of separate inventive subject matter in all cases.

Furthermore, Applicants have paid a filing fee for an examination of all the claims in this application. If the Examiner refuses to examine the claims paid for when filing this application and persists in requiring Applicants to file divisional applications for each of the groups of claims, the Examiner would essentially be forcing applicants to pay duplicative fees for the non-elected or withdrawn claims, inasmuch as the original filing fees for the claims (which would be later prosecuted in divisional applications) are not refundable.

Finally, Applicants note that upon allowance of a generic claim, Applicants will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. 1.141.

In view of the foregoing, Applicants respectfully request the Examiner to reconsider and withdraw the restriction requirement and examine all claims pending in this application.